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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/748,128 | 12/24/2003 | John C. Reed | 66821-0058 | 1734 |

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| EXAMINER | |
|---|---|
| AUDET, MAURY A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/748,128 | REED ET AL. | |
| | Examiner | Art Unit | |
| | Maury Audet | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 December 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

It is noted at the outset that method claims 35 and 36 claim dependency to claim 33 (drawn to a product), and that it is assumed Applicant has made a typographical error and meant dependency to method claim 34 and the restriction so applied (Applicant is asked to correct/verify this upon response).

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-5, 28-33 are drawn to an isolated agent, or pharmaceutical composition or composition thereof, comprising a core peptide or core structure selected from the group consisting of: core peptides 5 through 39 and 42 through 55 (or Figures/TPI #'s thereto); classified in class 530, subclass 300+.

II. Claims 6-7, drawn to a complex comprising an IAP bound to peptides and/or structures like Invention I and also TPI759 (i.e. Figure 8), TPI882 (i.e. Figures 7/10), TPI914 (i.e. Figures 4/5), or TIP927 (i.e. Figures 6/9)), classified in class 514, subclass 2.

III. Claims 8-12, 43-50, drawn to a method of derepressing an IAP-inhibited caspase comprising the use of peptides and/or structures, classified in class 424, subclass 1.69.

IV. Claims 13-16, drawn to a method of promoting apoptosis in a cell, using peptides and/or structures, classified in class 424, subclass 1.69+.

V. Claims 17-22, 34-36, 51-63, and 64-68, drawn to a method of reducing the severity of a pathologic condition of *cancer* using peptides and/or structures, classified in class 424, subclass 1.69+.

VI. Claims 17-22, 34-36, and 51-63, drawn to a method of reducing the severity of a pathologic condition of *psoriasis* using peptides and/or structures, classified in class 424, subclass 1.69+.

VII. Claims 17-22, 34-36, and 51-63, drawn to a method of reducing the severity of a pathologic condition of *hyperplasia* using peptides and/or structures, classified in class 424, subclass 1.69+.

VIII. Claims 17-22, 34-36, and 51-63, drawn to a method of reducing the severity of a pathologic condition of *autoimmune disease* using peptides and/or structures, classified in class 424, subclass 1.69+.

IX. Claims 17-22, 34-36, and 51-63, drawn to a method of reducing the severity of a pathologic condition of *restenosis* using peptides and/or structures, classified in class 424, subclass 1.69+.

X. Claims 23-27, drawn to a method of identifying an agent that derepresses an IAP-inhibited caspase using peptides and/or structures comprising detecting a labeled derepressor of an IAP-inhibited caspase bound to an IAP or caspase, classified in class 424, subclass 9.34+.

XI. Claim 37 and 39-42, drawn to a method for identifying an agent that derepresses an IAP-inhibited caspase using peptides and/or structures comprising contacting a BIR2 domain, classified in class 424, subclass 9.34+.

XII. Claims 38 and 39-42, drawn to a method of identifying an agent that derepresses an IAP-inhibited caspase using peptides and/or structures comprising detecting a labeled derepressor of a BIR domain-inhibited caspase, classified in class 424, subclass 9.34+.

The inventions are distinct, each from the other because:

Inventions I and II are related in that they both contain compounds comprising e.g. core peptides 5 through 39 and 42 through 55. However, Invention III also must contain an IAP bound to one of the above compounds. Thus, each invention is of different chemical and/or peptide and/or pharmaceutical substitutions, each invention differs in structure (chemically, physically, or pharmacologically) and in function.

Inventions I-II and III-XII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product, as evident by the myriad of compounds capable of use therein (namely, compounds comprising e.g. core peptides 5 through 39 and 42 through 55).

The methods of Groups III-XII are directed to different inventions, which are not connected in design, operation, and/or effect. These methods are independent since they are not

disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

**Requirement for Peptide/Structure Election**

The compounds comprising e.g. core peptides or structures of core peptides 5 through 39 and 42 through 55 (e.g. Groups I, III-XII) or a complex of an IAP and the latter (e.g. Group II), do not contain a distinguishable core sequence that runs through each; thus an individual sequence and/or structure search is required of each compound. Therefore, as part of the electing one of Groups I-XII as the elected invention, Applicant is required to elect a specific peptide/structure/compound/Figure/complex, which contains the core peptide or structure as drawn to the elected invention. The Examiner is willing to search more than one compound (Groups I, II-XII) or complex (Group II) provided such compounds contains a substantial, core structure there between, and that CORE THEREBETWEEN has been thoroughly SEARCHED in the relevant databases by Applicant and deemed to be NOVEL/UNOBVIOUS. Any teachings to the contrary would render a non-novel/unobvious core between more than one of the compounds useless, since a co-extensive search there between would no longer be possible, and an individual search of each compound then necessary to determine whether the non-core portion of each compound/structure is novel/unobvious over the teachings of the core therein). Applicant may wish to telephone the Examiner to discuss the compounds in question of such a latter election (after Applicant has carried out the relevant search as discussed above); should Applicant not choose to elect a single compound/structure as the invention, to which the elected

invention is to be examined as drawn to. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

**Species Election**

Additionally, this application contains claims directed to the following patentably distinct species of the claimed invention:

I. XIAP-inhibited caspases (i.e. caspase –3, -7, -9) (i.e. Group I);

II. IAP-inhibited caspase (i.e. XIAP, c-IAP-1, c-IAP-2, or survivin (i.e. Groups III-XII; if XIAP elected a specific one must be elected as noted above in Species I);

III. A second therapeutic agent (e.g. anti-cancer drug for cancer) for any of Groups V-IX (cancer, psoriasis, hyperplasia, autoimmune disease, or restenosis); and/or

IV. A specific autoimmune disease (should Group VIII be elected as the invention).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1,2, 5, 6, 8, 13, 17, 23, 28, 33, 37, 38, 43, 51, and 64 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***In re Ochiai/Brouwer Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the**

**patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 04/28/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654